



MOLBIO DIAGNOSTICS PRIVATE LIMITED

ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

Mfg. Lic. No.: MFG/IVD/2019/000018

Date:06/07/2022

Doc ID: COA/TN/HV013

BRAND NAME	Truenat® HIV-1		
GENERIC NAME	Chip-based Real Time PCR Test for HIV-1 Virus		
LOT No.	HV013	CHIP LOT NO.	HDLW431
MFG. DATE	2022-06	EXP. DATE	2024-05
PACK SIZE	5T, 20T, 25T, 50T		
STORAGE	2°C to 30°C		A.R. No.:B-HV-013a

PRECAUTION: Refer Safety Data Sheet and Instructions for Use.


Sr. No.	Components in each kit	Specification	Observation
1	Pouch contains 1 chip, 1 micro tube, 1 dessicant pouch and 1 filter barrier tip	5 no, 20 no,25 no. 50 nos.	Pass
2	Colour of desiccant pouch	Orange	Pass
3	Package insert	01 no.	Pass

PERFORMANCE		
CONTROLS	(Ct Values)	
Specificity Tests	HIV-1	Control
Negative Control	ND	29.17
	ND	27.75
Positive Control	28.4	27
	28.17	26.71
	27.6	25.83
	26.75	26.25
	28.6	26.56
	28.17	26.75
	28.4	26.6
	29	27.11
Average	28.26	26.6
Standard deviation	±0.44	± 0.40

\*ND- Not detected, Ct- Cycle threshold, HIV-1- Human Immunodeficiency Virus type 1

\*A deviation of  $\leq 1.5$  is acceptable for Ct values

MANUFACTURING RECORDS ARE VERIFIED, CHECKED AND PRODUCT IS MANUFACTURED AS PER THE MASTER FORMULA, SAMPLES TESTED AND LOT IS QC APPROVED FOR SALE

  
QUALITY CONTROL  
Name: Dr. Praveen Kumar  
Designation: QC Head

**Molbio Diagnostics Private Limited**

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